PATENT

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Application No.:		10/647,619	Confirmation No.: 2861
Applicant	:	Dennis A. Boismier et al.	
Filed	:	August 25, 2003	
TC/A.U.	:	1742	
Examiner	:	Wyszomierski, George P.	
Title	:	SELECTIVE TREATMENT OF LINEAR ELASTIC MATERIALS TO PRODUCE LOCALIZED AREAS OF SUPERELASTICITY	
Docket No.	:	1001.1689101	
Customer No.	:	28075	

PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENT

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Commissioner for Patents
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By JoAnn Lindman
JoAnn Lindman

Dear Sir:

Appellants have carefully reviewed the Final Office Action dated May 9, 2006 and the Advisory Action dated July 12, 2006. Currently, claims 1-27 are pending in the application, claims 1-22 have been withdrawn from consideration, and the Examiner has rejected claims 23-27. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

The Examiner has maintained that claims 23-27 are obvious and/or anticipated by various references. For a detailed list of these rejections, and the most recent detailed response from the Appellants, please see the response dated July 5, 2006. However, Applicants point out that none of the references cited by the Examiner, either together or in combination, disclose a linear elastic member that has at least one localized area of flexibility formed by selectively heating at

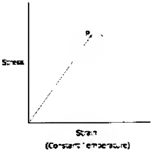
least a portion of the member to a temperature sufficient to induce superelasticity, as recited by claim 23.

The Examiner maintained the rejection of all the claims, stating in the Advisory Action:

> Applicant appears to be attempting to define a difference between a "linear elastic" material as claimed, and one that is superelastic, shape memory, or Nitinol. However, "linear elastic" merely describes the stress-strain behavior of a material, and is not mutually exclusive with any of the other mentioned features. Applicant has presented no evidence that claimed material possesses any property (e.g. linear elastic behavior) not present in any of the prior art materials.

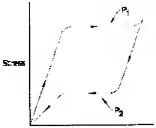
From this statement, it is apparent that the claim terms linear elastic and superelastic are causing some confusion. In claim 23, the Appellants are claiming a device that has a member that is linear elastic, where at least one localized area of the member has been treated to make it superelastic. The Examiner is incorrect in making the statement that "'linear elastic' merely describes the stress-strain behavior of a material, and is not mutually exclusive with any of the other mentioned features." It appears from this statement that the Examiner believes that a material that is superelastic or shape memory is, or can be, linear elastic as well. This is not an accurate characterization of such materials. Materials that are superelastic have properties that are different (and mutually exclusive from) properties of materials that exhibit linear elasticity.

The terms linear elasticity and superelasticity describe two very different types of elasticity. Linear elasticity means that a material has a stress-strain curve that is substantially linear. An example idealized stress-strain curve of a linear elastic material is reproduced below:



As shown in this graph, the portion of the curve between the origin and the point P, sometimes called the proportional region of the curve, can be substantially linear. Past the point P (sometimes called the proportional limit of the material), the material becomes deformed, and will not fully recover its original shape. If the stress is removed from the material before the material reaches the point P, the material can return to, or near to, the origin, in some cases substantially along the same line.

In contrast, materials that are characterized as superelastic generally have a very different stress-strain curve and have two crystal phase structures. The two phases are called austenite and martensite. An idealized curve of a superelastic material is reproduced below, where the arrows show the direction of the path taken by the material through a stress-strain cycle.



Such a superelastic stress-strain curve is very different from a linear elastic curve. As the material is placed under strain, the curve initially has a relatively steep slope. At a certain point, however, the slope flattens out. This area of the curve is marked as P_1 in the above graph, and is often called the "superelastic flag," or "superelastic plateau," portion of the curve. Generally, under certain conditions, stressing superelastic materials can cause the material to change from its austenite to its martensite crystal structure. Such production of the martensite phase is often called stress-induced martensite. Further, under certain conditions, when the stress is removed from the material, the material will seek out, and return to, its original austenite phase. As it returns to the austenite phase from its stress-induced martensite phase, it can go through another superelastic plateau, as shown in the graph at P_2. Without being bound by the theory, the driving force behind superelasticity (and the presence of the superelastic plateaus in the stress-strain curve) is thought to be the change in the crystal structure of the material between austenite and martensite. In contrast, linear elastic materials normally do not have a phase change in the elastic, or proportional, region of the curve.

As a further note, the superelastic materials described above can also exhibit shape memory properties under certain conditions. Shape memory is the ability of a material to be deformed and later assume its original shape. With the above described superelastic materials, certain temperature changes can typically cause the material to return to its original shape. Shape memory materials are typically originally in an austenite state. The material can be stressed, causing the formation of stress-induced martensite. However, the material may be at a temperature at which, when the stress is removed, the material does not revert to its austenite

phase. As such, there is no driving force to cause the material to be elastic in such a case. Rather, the material will remain deformed until the material is exposed to a temperature that causes the material to revert to the austenite crystal phase. This return to the austenite phase can return the material to its original shape; in this way, the shape memory material "remembers" its original shape. An idealized stress-strain curve that describes this behavior is shown below:

The curve shows that two-phase shape memory materials can have a superelastic plateau on the extension portion of the curve (again, this plateau is marked P_1). However, when the stress is released, the material does not immediately recover all of the strain. All or a portion of the strain can be recovered by changing the temperature of the material, causing the material to return to its austenite phase and returning the strain (and in the process the original shape) along the dotted line shown on the curve.

The current application also highlights some of the above differences in properties, along with at least one additional difference. Figure 4 of the current application compares the stress-strain curves of a linear elastic and superelastic material. Again, the different shapes of the curves are shown in this figure. Also, the two graphs show a difference in the ultimate strength of a comparable linear elastic and superelastic material (with the ultimate strength of a linear elastic material being the greater of the two).

As can be observed from the above graphs (and Figure 4 of the current application), materials that exhibit linear elasticity have significantly different properties when compared to materials with superelasticity or shape memory, and linear elastic and superelastic/shape memory materials are mutually exclusive classes of materials. The different shape of the superelastic/ shape memory curves (again, thought to be caused by the change in the crystal structure of these materials) can allow elongate medical devices to more efficiently navigate tight turns in a patient's anatomy. Specifically, the superelastic plateau region of the curve can allow these materials to be bent relatively easily within a certain region (the plateau region) of their stress-

strain curves. On the other hand, if it is desired to provide for greater strength and force transfer along all or a portion of a device, a linear elastic material can be more appropriate. Although the linear elastic material may in some cases have less flexibility, it can have greater ultimate strength and can provide for transmission of greater forces. As such, these materials have significantly different properties, and a linear elastic material cannot be considered the equivalent of a superelastic or shape memory material.

Further, as noted in the current application (see paragraph [0024]), some linear elastic materials (e.g., some linear elastic Nitinol alloys) can be treated in order to make the material have austenite and martensite crystal structures, giving the material superelastic and/or shape memory properties. In the same way that hardened steel would not be the same as unhardened steel, these linear elastic and superelastic materials are simply not the same thing even though they may have the same stoichiometric ratio of components.

The discussion above highlights that superelastic/shape memory materials are very different from linear elastic materials, and these different materials cannot be considered equivalents of one another. As such, it cannot be said that the superelastic and shape memory materials (including the superelastic and shape memory Nitinol alloys) disclosed in any one reference (or in any combination of these references) cited by the Examiner are the same as the linear elastic member that has at least one localized area of flexibility that has been treated to make it superelastic, as recited in claim 23. Therefore, this claim, and claims 24-27 that depend therefrom, cannot be anticipated or rendered obvious by the cited references.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

Date: Sept. 13, 2006

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